

MEMORANDUM

DATE: 8/6/96

SUBJECT: ID#96CA0036. SECTION 18 EXEMPTION FOR THE USE OF
MYCLOBUTANIL ON ASPARAGUS IN THE STATE OF CALIFORNIA.

DP Barcode:	D227978	Caswell:	723K
Trade Name:	Rally 40W	Chem#:	128857
Reg#:	707-215	Case#:	287968
Class:	Fungicide	40 CFR:	180.443

TO: D. Deegan/M. Johnson, PM Team 41
ERMUS/RSB/RD (7505W)FROM: M. Nelson, W. Dykstra, and C. Lewis
Pilot Interdisciplinary Risk Assessment Team
RCAB/HED (7509C)THRU: Michael S. Metzger, Acting Chief
RCAB/HED (7509C)INTRODUCTION

The California Department of Agriculture requests a §18 specific exemption for the use of myclobutanil on asparagus for control of asparagus rust. This is the first §18 request for this use. The proposed program will entail application of 2,812.5 gallons of Rally 40W Agricultural Fungicide in Water-Soluble Pouches (EPA Reg. No. 707-215) on 18,000 acres in the counties of San Joaquin, Sacramento, Contra Costa, Santa Barbara, and Imperial. The §18 will be in effect from 7/9/96 - 11/30/96.

RECOMMENDATION

Occupational exposure and dietary risk estimates do not exceed HED's level of concern. **Provided the Section 18 label specifies a restricted entry interval of 48 hours,** HED has no objection to the issuance of this Section 18 exemption for the use of myclobutanil on asparagus in the State of California. An agreement should be made with FDA regarding the legal status of the treated asparagus in interstate commerce.

CONCLUSIONS

Hazard Assessment

1. Occupational Exposure Endpoint Selection

- a) Short-Term Risk. For short-term dermal margin of exposure (MOE) calculations, the TES Committee recommended use of the systemic NOEL of 100 mg/kg/day from the 21-day dermal toxicity study in rats (MRID# 00266080). This dose level was the highest tested in the study. The TES Committee did not identify an inhalation endpoint.
- b) Intermediate-Term Risk. For intermediate-term MOE calculations, the TES Committee recommended use of the NOEL of 10 mg/kg/day from the 2-generation rat reproduction study (MRID#s 00143766, 00149581). At the LEL of 50 mg/kg/day, there were decreases in pup body weight, an increased incidence in number of stillborns, and atrophy of the prostate and testes.
- c) Chronic Risk. For chronic MOE calculations, the TES Committee did not recommend a study, and there is no chronic exposure scenario with this §18 action.
- d) Cancer Risk. Myclobutanil was classified by the RfD/Peer Review Committee as a Group E chemical - "evidence of non-carcinogenicity for humans".
- e) Dermal Penetration. For short-term MOEs, a dermal toxicity study was used, and dermal penetration data were not applied. For intermediate-term MOEs, 100% dermal penetration (default value) was used.

2. Dietary Endpoint Selection

- a) Acute Risk. The TES Committee has not identified an acute dietary toxicological endpoint.
- b) Chronic Risk. The RfD of 0.025 mg/kg/day was established by the RfD/Peer Review Committee based on the chronic

feeding study in rats (MRID#s 00149582, 00165247) with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100 based on testicular atrophy at the LEL of 9.9 mg/kg/day.

- c) Cancer Risk. Myclobutanil was classified by the RfD/Peer Review Committee as a Group E chemical - "evidence of non-carcinogenicity for humans".

Occupational Exposure

1. Acute data for this formulation are available (Tox Oneliners). The proposed work clothing and personal protective equipment (PPE) listed on the label (long-sleeved shirt, long pants, water-proof gloves, shoes plus socks, protective eyewear, and chemical-resistant headgear for overhead exposure) are in compliance with the Worker Protection Standard (WPS).
2. Acute toxicological data (based on Tox Oneliners) for the technical are as follows: category I for primary eye irritation; category III for acute oral and dermal LD50; category IV for primary dermal irritation and acute inhalation LD50. The restricted entry interval (REI) of 24 hours appearing on the label is not in compliance with the WPS. **To be in compliance with the WPS, the Section 18 label should specify an REI of 48 hours.**
3. Occupational exposure assumptions and estimates of exposure are summarized in Tables 1 and 2, respectively. (Note: The TES Committee did not identify a short-term inhalation endpoint. Consequently, PIRAT has only prepared dermal estimates of exposure for workers.)

Currently, PHED lacks sufficient data for wettable powders in water-soluble pouches. Use of water-soluble pouches would be expected to significantly reduce exposure. This §18 entails use of Rally 40W (EPA Reg. No. 707-215) in water-soluble pouches. Thus, the estimates of exposure for mixer/loaders should be considered very conservative.

Dietary Exposure

1. The nature of the residue in plants is adequately understood. The residue of concern is myclobutanil plus its alcohol metabolite (free and bound), as specified in 40 CFR 180.443(a).
2. An adequate enforcement method (Rohm and Haas Method 34S-88-10, MRID# 408033-02, quantitation is by GLC using an N/P detector for myclobutanil and an EC detector for residues measured as the alcohol metabolite) is available to enforce the tolerance expression. A copy is on file in PP#4E4302.

3. Combined residues of myclobutanil plus its alcohol metabolite in/on asparagus are **not expected to exceed 0.02 ppm** as a result of this Section 18 use.
4. Secondary residues are not expected in animal commodities as no feed items are associated with this Section 18 use.

Dietary Exposure**Table 3. Residue Considerations Summary Table**

PARAMETER	PROPOSED USE	COMPARISON RESIDUE DATA
CHEMICAL	Myclobutanil	Myclobutanil
FORMULATION	Rally 40W (EPA Reg. No. 707-215-AA) (packaged in water-soluble pouches)	Rally 40W (707-215 or 707-221)
CROP	Asparagus	Asparagus (two 1995 CA field trials)
TYPE APPLICATION	Ground (≥ 30 gpa) or air (≥ 20 gpa).	Ground - foliar to asparagus ferns
# APPLICATIONS	4	4
TIMING/PHI	Fern stage: Begin at first sign of disease and continue on a 14-21 day schedule. Discontinue 30 days before harvest.	During fern stage; applications were made at 14 ± 2 day intervals (mid-July to late August). After 4th application, ferns were mowed to stimulate spear development. PHI = 30 days.
RATE/APPLICATION	0.31 lb (0.125 lb ai)/A	0.31 lb (0.125 lb ai)/A
RATE/SEASON	1.25 lbs (0.5 lb ai)/A	1.25 lbs (0.5 lb ai)/A
MAXIMUM RESIDUE	N/A	< 0.01 ppm <u>each</u> of parent and metabolite
OTHER RESTRICTIONS	Always include spray adjuvant (such as Latron B-1956 or CS-7) in spray mix.	Apply with a spray adjuvant, such as Latron B-1956 or CS-7.
RESIDUE DATA SOURCE	N/A	Presubmission field trials data faxed by IR-4, 7/23/96 (ID# A5414.95-DEL07)
PERFORMING LAB	N/A	IR-4

ATTACHMENT: Chronic DRES Analysis (8/1/96)

cc (with Attachment): M. Nelson, PIRAT, SAB (B. Steinwand).

cc (without Attachment): W. Dykstra, C. Lewis, OREB (#128857),
Caswell File (#723K), CBTS (\$18), TOX I (P. Hurley).

RDI:DSDavis:8/5/96:EDoyle:8/5/96:PIRAT:8/6/96

[mjn file: MYCL-ASP.S18]

